K014108
p1/2

JAN 1 0 2002

Section 2 Summary & Certification

510(k) Summary of Safety and Effectiveness

Date: December 13, 2001

Submitter: GE Medical Systems - *Information Technologies*
8200 W. Tower Ave.
Milwaukee, WI 53223 USA

Contact Person: David Wahlig
GE Medical Systems - *Information Technologies*
Phone: (262) 293-1705
Fax: (414) 371-3736

Contact Person: Karen Webb
GE Medical Systems - *Information Technologies*
Phone: (414) 362-3329
Fax: (414) 371-3736

Trade/Proprietary Name: MAC 5000 ECG Analysis System

Common/Usual Name: Electrocardiograph

Classification Names & Citations:

21 CFR 870.1425	Programmable diagnostic computer	74DQK
21 CFR 870.2920	Transmitters and Receivers, Electrocardiograph, Telephone	74DXH
21 CFR 870.2340	Electrocardiograph	74DPS
21 CFR 870.2340	System, ECG Analysis	74LOS
21 CFR 870.1025	Detector and Alarm, Arrhythmia	74DSI

Predicate Devices: Mac 5000 Rest ECG Analysis System K#991735
GE Marquette ECG Analysis Program K#002209
ACI TIPI Algorithm K#974199
MAX 1 System K#890323

Device Description: The Mac 5000 ECG Analysis System is designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The device consists of two basic components: the processing unit and patient acquisition module. Models provide rechargeable battery operation and/or optional trolley for transporting the equipment.

The MAC 5000 can deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

Intended Use: The MAC 5000 ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner. The MAC 5000 is intended to be used by trained operators in a hospital or medical

professional's facility environment to record ECG signals from surface electrodes. The device is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations.

Technology: The technological characteristics of the MAC 5000 device have been updated to reflect use of current technology and to incorporate user-requested features. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety or effectiveness.

Test Summary: The MAC 5000 complies with the voluntary standards as detailed in Section 9 of this submission.

The following quality assurance measures were applied to the development of the MAC 5000.

- Requirements specification reviews
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final system validation

Conclusion: The MAC 5000 is a modification to GEMS-IT's existing MAC 5000 device incorporating features that have been previously cleared under different 510(k)'s. This premarket notification submission demonstrates that the MAC 5000 ECG Analysis System is substantially equivalent to the cleared MAC 5000 ECG Analysis System because this device has the same basic intended use and the differences in technological characteristics do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Mr. David Wahlig
Senior Regulatory Affairs Specialist
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K014108
Trade Name: MAC 5000 ECG Analysis Systems
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: December 13, 2001
Received: December 13, 2001

Dear Mr. Wahlig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

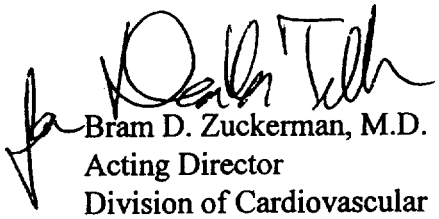
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Unknown; 510(k) filed on 13 December, 2001

Device Name: MAC 5000 ECG Analysis System

K014108

Indications For Use:

The MAC 5000 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014108

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)